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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 10/030,251 | 01/09/2002 | Katsumasa Harada | 740709-493 | 8831 |
| 22204 | 7590 | 10/20/2004 | EXAMINER | |
| NIXON PEABODY, LLP 401 9TH STREET, NW SUITE 900 WASHINGTON, DC 20004-2128 | | | COLEMAN, BRENDA LIBBY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1624 | |

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,251

Applicant(s)

HARADA ET AL.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7,9-11 and 14-22 is/are pending in the application.
- 4a) Of the above claim(s) 10,11 and 14-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

Claims 1, 2, 4, 5, 7, 9-11 and 14-22 are pending in the application.

This action is in response to applicant's amendment filed August 3, 2004. Claims 1, 2, 4, 5, 7 and 9 have been amended and claims 3, 6, 12 and 13 have been canceled.

Response to Amendment

Applicant's amendments and arguments filed August 3, 2004 have been fully considered with the following effect:

1. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection of claim 13, labeled paragraph 5 in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections of claims 1-7, 9, 12 and 13, labeled paragraph 6 in the last office action, which are hereby **withdrawn**.
3. The applicant's amendments and arguments are sufficient to overcome the 35 U.S.C. § 102, anticipation rejection of claims 1, 2, 4, 5, 7 and 9, labeled paragraph 7 in the last office action, which is hereby **withdrawn**.

In view of the amendment dated August 3, 2004, the following new grounds of rejection apply:

Election/Restrictions

4. Claims 10, 11 and 14-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable

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generic or linking claim. Election was made without traverse in the paper filed January 12, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by BENNETT et al., Organic Preparations and Procedures Int. BENNETT teaches the process of preparing the dibenzothiazepines of the instant invention where 1-iodo-2-nitrobenzene of formula (1) is reacted with 5-methoxythiosalicylic acid of formula (2) forming the compounds of instant formula (3). 2-carboxy-4-methoxy-2'-nitrodiphenyl sulfide of formula (3) is reacted with ferrous ammonium sulfate to obtain 2'-amino-2-carboxy-4-methoxydiphenyl sulfide of instant formula (4). 2'-amino-2-carboxy-4-methoxydiphenyl sulfide of instant formula (4) is then subjected to dehydration-condensation to obtain the 2-methoxydibenzo[b,f](1,4)thiazepin-11(10H)-one compound of instant formula (5).

6. Claims 1, 2, 4, 5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by KUTI et al., Phosphorus, Sulfur and Silicon. KUTI teaches the process of preparing the dibenzothiazepines of the instant invention where 2-iodo-nitrobenzene of formula (1) is reacted with thiosalicylic acid of formula (2) forming the compounds of

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instant formula (3). 2-(2-nitrophenylthio)benzoic acid of formula (3) is reacted with ferrum reductum and crystalline iron(III) chloride to obtain 2-(2-aminophenylthio)benzoic acid hydrochloride of instant formula (4). 2-(2-trifluoroacetylaminophenylthio)benzoic acid is then subjected to dehydration-condensation to obtain the dibenzo[b,f][1,4]thiazepin-11(10H)one compound of instant formula (5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2, 4, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over BENNETT et al., Organic Preparations and Procedures Int. BENNETT teaches the process of preparing dibenzothiazepine compounds from the corresponding nitrobenzene, thiosalicylic acid, 2-nitro-2'-carboxy-diphenylsulfide, 2-amino-2'-carboxy-diphenylsulfide compounds of formulae (1), (2), (3) and (4) respectively as claimed herein. BENNETT differs only in the nature of the preparation of formula IV, methyl 5-methoxythiosalicylate used as an intermediate between the 5-methoxythiosalicylic acid and the reaction with 1-iodo-2-nitrobenzene. The preparation of the compounds of the instant invention, formula (5) and the process taught in the reaction scheme on page 287 comprises all of the steps claimed herein. Thus teaching the process of preparing dibenzothiazepine compounds by the same process as

claimed in the instant invention. Thus, one of ordinary skill in the art would have been motivated to use the process of BENNETT to prepare the compounds of the instant invention where 1-iodo-2-nitrobenzene of formula (1) is reacted with 5-methoxythiosalicylic acid of formula (2) forming the compounds of instant formula (3), the 2-carboxy-4-methoxy-2'-nitrodiphenyl sulfide of formula (3) is reacted with ferrous ammonium sulfate to obtain 2'-amino-2-carboxy-4-methoxydiphenyl sulfide of instant formula (4), the 2'-amino-2-carboxy-4-methoxydiphenyl sulfide of instant formula (4) is then subjected to dehydration-condensation to obtain the 2-methoxydibenzo[b,f](1,4)thiazepin-11(10H)-one compound of instant formula (5).

8. Claims 1, 2, 4, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over KUTI et al., Phosphorus, Sulfur and Silicon. KUTI teaches the process of preparing dibenzothiazepine compounds from the corresponding nitrobenzene, thiosalicylic acid, 2-nitro-2'-carboxy-diphenylsulfide, 2-amino-2'-carboxy-diphenylsulfide compounds of formulae (1), (2), (3) and (4) respectively as claimed herein. KUTI differs only in the nature of the preparation of formula 13, where 2-(2-nitrophenylthio)benzoic acid is reacted with ferrum reductum ($\text{Fe}/\text{Fe}_2\text{O}_3$) and crystalline iron(III) chloride of which the combination as a whole is a ferrous salt to obtain 2-(2-aminophenylthio)benzoic acid hydrochloride. KUTI also differs in the preparation of dibenzo[b,f](1,4)thiazepin-11(10H)-one where 2-(2-trifluoroacetylaminophenylthio)benzoic acid is used as an intermediate between the 2-(2-aminophenylthio)benzoic acid hydrochloride and the dehydration-condensation to prepare the dibenzothiazepine compounds of instant formula (5). The preparation of

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the compounds of the instant invention, formula (5) and the process taught in the reaction scheme on page 120 comprises all of the steps claimed herein. Thus teaching the process of preparing dibenzothiazepine compounds by the same process as claimed in the instant invention. Thus, one of ordinary skill in the art would have been motivated to use the process of KUTI to prepare the compounds of the instant invention where 2-iodo-nitrobenzene of formula (1) is reacted with thiosalicylic acid of formula (2) forming the compounds of instant formula (3). 2-(2-nitrophenylthio)benzoic acid of formula (3) is reacted with ferrum reductum and crystalline iron(III) chloride to obtain 2-(2-aminophenylthio)benzoic acid hydrochloride of instant formula (4). 2-(2-trifluoroacetylaminophenylthio)benzoic acid is then subjected to dehydration-condensation to obtain the dibenzo[b,f][1,4]thiazepin-11(10H)one compound of instant formula (5).

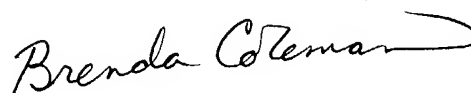
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in cursive script that reads "Brenda Coleman". The signature is written in dark ink and includes a long, sweeping horizontal stroke at the end.

Brenda Coleman
Primary Examiner
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October 14, 2004